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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,159	01/13/1999	Allan Balmain	CCI-005US	7671
959	7590	06/03/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			SCHNIZER, RICHARD A	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/14

Office Action Summary

Application No.

09/051,159

Applicant(s)

BALMAIN ET AL

Examiner

Richard Schnizer, Ph. D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 15, 18-22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-11, 13, 15, 18-22 and 25 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Examiner Amendment and Raw Sequence Listing Error Report.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Cynthia Kanik on 5/26/04.

IN THE CLAIMS:

Claim 1 (Currently amended) A composition comprising a first nucleic acid construct comprising a first gene encoding an antitumor agent whose expression is controlled by a first promoter whose function is suppressed by a wild-type p53 allele in non-tumor cells relative to tumor cells in which wild-type p53 tumor suppressor function is abrogated, and a second nucleic acid construct comprising a second gene whose gene product suppresses expression of said first gene, wherein the expression of said second gene is controlled by a second promoter [that comprises a p53 binding site and] comprising the sequence 5'-PuPuPuC(A/T)(A/T)GPyPyPy-3' (SEQ ID NO:1) and whose function is up-regulated by wild type p53 in non-tumor cells relative to tumor cells in which wild-type p53 tumor suppressor function is abrogated, such that said first gene is expressed in tumor cells and suppressed in non-tumor cells.

In claims 6 and 7, delete "*Drosophila*" and substitute --*Drosophila*-- therefor.

Cancel claim 12.

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Claim 13 (Currently amended) The composition according to claim [12] 1 wherein said second nucleic acid construct comprises [said p53 binding site sequence] SEQ ID NO:1 downstream of a TATA Box and downstream of the transcriptional start site of said second promoter of said second nucleic acid construct.

In claim 15 delete 'the HSP70' and substitute --a HSP70-- therefor.

Claim 20 (Currently amended) [A] An isolated cell containing [a] the first nucleic acid construct and [a] the second nucleic acid construct of [a] the composition according to claim 1.

22. (Currently amended) A method of controlling the proliferation of a tumor cell comprising introduction of [a] the first nucleic acid construct and [a] the second nucleic acid construct of the composition according to claim 1 into the cell in vitro.

25. (Currently amended) The composition of claim 1, wherein said first promoter is selected from the group consisting of [the] a HSP70 promoter, [the] a Bcl-2 promoter, [the] a PCNA promoter, [the] a MDR1 promoter, [the] a CMV promoter and [the] a p16^{INK4} promoter.

Compliance with Sequence Rules

The Sequence Listing filed on 5/7/04 contains errors as noted in the attached Raw Sequence Listing Error Report. Correction is required.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37

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CFR 1.821 through 1.825 for the following reason(s). This application clearly fails to comply with the requirements of 37 C.F.R.1.821-1.825. Applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). **The Sequence Listing filed on 5/7/04 contains errors as noted in the attached Raw Sequence Listing Error Report. Correction is required. Also, Fig. 4 contains nucleic acid sequences in excess of 9 bases that are not accompanied by a SEQ ID NO.** If these sequences are listed in the current Sequence Listing, then the brief description of the Figure, or the Figure itself, should be amended to include the appropriate SEQ ID NOS. If these sequences are not in the current Sequence Listing, then Applicant must provide:

A substitute computer readable form (CRF) copy of the "Sequence Listing".

A substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

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Drawings

Figure 11 is objected to because although the specification describes Figure 11D at page 25, lines 17-19, Figure 11 has no panel labeled 'D'. Correction of the drawing is required.

Conclusion

This Examiner's Amendment overcomes the written description rejection set forth in the previous Office Action mailed 9/10/03, and combined with Applicant's amendments, places the claims in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.



DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.